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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,355	02/14/2002	Hildegard M. Kramer	5190	8887

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GENZYME CORPORATION
LEGAL DEPARTMENT
15 PLEASANT ST CONNECTOR
FRAMINGHAM, MA 01701-9322

EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/075,355	Applicant(s) KRAMER ET AL.	
	Examiner Joseph T. Woitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-13,15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-13,15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application claims benefit to provisional application 60/268,559, filed February 14, 2001.

Applicants' amendment filed November 15, 2005, has been received and entered. The specification has been amended. Claims 1 and 6 have been amended. Claims 7, 14 and 17-54 have been cancelled. Claims 1-6, 8-13, 15 and 16 are pending.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on July 12, 2004, was acknowledged. No new arguments have been provided and the requirement is still deemed proper and FINAL.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-6, 8-13, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically;

Claim 1(b) recites “a desired shape” and the metes and bounds of the claim are indefinite because what would be “desired” is a relevant term subject to interpretations based on an artisans need or want. The claim is indefinite because a single embodiment while it may be desirable in one case, it may not be in another. Dependent claims fail to further clarify the basis of the rejection to indicate what is desirable, and to some extent complicate the interpretation because they provide further method steps that modify the final product made by claim 1.

Claim 11 is confusing and unclear in the recitation of “after at least one of the freezing step and the vacuum-drying step” because claim 1 appears to require that both the freezing and vacuum-drying steps must be practiced and that shredding could not occur until the complete method is practiced. Further, it renders claim 1 unclear in what number or type of steps can be performed throughout the practice of claim 1, or if step c) is a requirement of claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 8-13, 15 and 16 rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca *et al.*, Yannas *et al.*, Allen *et al.* (US Patent 4,962,172) and Solomon *et al.* (US Patent 5,484,604) is withdrawn.

As indicated in Applicants' arguments, the amendment to claim 1 to include specifically, that the macromer has a cross-linkable group for free radical polymerization and that a free radical chain reaction method step is used differentiates the claimed invention from that taught by DeLuca *et al.*, Yannas *et al.*, Allen *et al.* and Solomon *et al.* More specifically the claims have been amended to narrow the scope to exclude the cross-linking materials taught in the cited references.

Claims 1-6, 8-13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbell *et al.* (US Patent 5,410,016), McGregor *et al.*, Vyakarnam *et al.* and Sioussat *et al.* (references provided in IDS)

At the time of filing photopolymerizable macromers were known. Hubbell *et al.* (US Patent 5,410,016) teach biocompatible and biodegradable hydrogels formed by free radical polymerization. The free radical polymerization is accomplished by the use of free radical initiators and the use of UV and visible light, or thermal energy (see summary in abstract). Hubbell *et al.* teaches that the hydrogels can be used in a variety of applications which include

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the addition of other biological macromolecules for *in vitro* and *in vivo* uses (see for example working examples for reduction to practice and analysis of particles made). Hubbell *et al.* proposes the use of the photopolymerizable macromers to produce products for controlled drug delivery, tissue coatings and tissue supports (see for example columns 9-11). Hubbell *et al.* provide general guidance and considerations for the use of the polymers formed for controlled drug delivery, tissue coatings and tissue supports, however fails to provide guidance to specific method steps that result in any specific product. At the time of filing each McGregor *et al.*, Vyakarnam *et al.* and Sioussat *et al.* teach methods of producing biopolymers for use in tissue repair and reconstruction. More specifically, each provide the specific method steps for generating a biopolymer where the biopolymer is first frozen and freeze dried before cross-linking. For example, Sioussat *et al.* teach that the crosslinking step can be performed after the freeze-drying step (see page 3, lines line 21, for example). The methods of McGregor *et al.* provide a method where dispersion is used to generate the structure and specifically require that the composition be frozen before cross-linking to establish the desired three dimensional structure of the resulting matrix (see summary in the abstract). Each McGregor *et al.*, Vyakarnam *et al.* and Sioussat *et al.* provide the guidance to make polymers with know structure(s) and orientation(s), and Hubbell *et al.* provide the materials and specific suggestion to make such materials using photopolymerizable macromers.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the polymers disclosed by Hubbell *et al.* and a suggested to produce products with defined structures using the specific methods disclosed by McGregor *et al.*, Vyakarnam *et al.* and/or Sioussat *et al.* Hubbell *et al.* provide clear suggestion and

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motivation for the use of the disclosed cross-linking agents in a variety of applications, but would require detailed methodology as exemplified by McGregor *et al.*, Vyakarnam *et al.* and Sioussat *et al.* to result in a product with desired characteristics.. One having ordinary skill in the art would have been motivated to use any known methodology for polymerization of a given polymer to provide a final product with a given structure/shape related to its ultimate intended use. There would have been a reasonable expectation of success given the specific results in each of the cited references demonstrating the level of skill in the art for making polymers with defined attributes.

Thus, the claimed invention as a whole was clearly *prima facie* obvious.

Conclusion

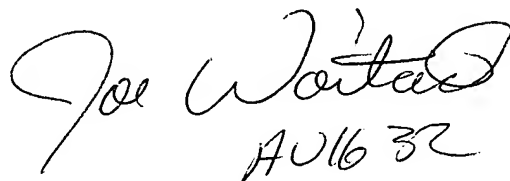
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach



Joe Woitach
AUL632